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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|--------------------|
| 10/610,339 | 06/30/2003 | Robert R. Alfano | 81424CIP | 6566 |
| 7590 | 05/05/2006 | | EXAMINER | |
| KRIEGSMAN & KRIEGSMAN 665 Franklin Street Framingham, MA 01702 | | | | HORWAT, JENNIFER A |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 3768 |

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/610,339 | ALFANO ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Horwat | 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 June 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 30 June 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/19/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Statutory Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-35 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6587711. This is a double patenting rejection.

Non-Statutory Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6587711. Although the conflicting claims are not identical, they are not patentably distinct from each other because the means plus function language of claim 1 part (h) provides for two types of means for transmitting the output of the detector to the computer, namely wired and wireless. The prior patent only claims the use of a wireless transmitter, however it would be an obvious modification that a transmitting device may be either wired or wireless, which is well known in the computer electronics art.

5. Claim 36 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6587711 in view of Farkas, et al (US 2004/0097790). The prior patent claims, in identical language, all limitations of claim 36 except for the means for moving optics relative to a sample to provide a variable lens. Farkas also discloses an endoscope for examining tissue and further teaches a movable lens system (paragraph 15) that provides the ability to image the surface or subsurface (paragraph 13). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the claims of the prior patent in light of the teachings in the reference by Farkas to include a moving lens system, as Farkas states it is desirable variable magnification of tissue within a body cavity (paragraph 8).

Claim Interpretation

6. Claims 1, 7, 32, and 36 appear to be invoking 35 U.S.C. 112, sixth paragraph due to the use of means plus functional language. Therefore the claim is interpreted to

include the limitations as described in the specification and their equivalents. The means for "transmitting the output" are interpreted to include both wired and wireless transmission and their equivalents. The means for "moving said optics" are interpreted to include a retractable mechanism and a movable platform and their equivalents.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 4, 10-18, 21, 24, 25, 26, 28, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Cook, et al (US 2002/0111546). Cook discloses an apparatus suitable for use in examining, for example the skin and mucosa, including a spectrometer for illumination of an object at one or more wavelengths (paragraph 7) in which each light source is polarized (paragraph 46), as is known in the art. The orientation of the polarizer may be adjusted. It is disclosed that the light source may be a plurality of LEDs, each emitting a different wavelength of light, such as green, blue, and red, wherein the source may be configured, or controlled, to emit a particular wavelength of light by means of one or more LEDs (paragraph 107). Alternatively, the light may be a light bulb, which would provide white light, and a means of spectral selection such as a colored filter (paragraph 7), such as the red and green filters

explicitly disclosed (paragraph 100). Light is used in both the visible and near infrared range (paragraph 6). A detector, such as a camera may be used to detect the light and capture an image. Optics, such as lenses are used in the system, and the illumination is detected by the image capturing device (paragraphs 16 and 67). Additionally, imaging optics such as magnifying optics may also be included (paragraph 98). A computer system is coupled to the image capturing means and carries out image processing steps (paragraph 44). The processing station also provides a display (paragraph 175). Memory is used which may be of many forms including a removable storage device (paragraph 163). The transmission from the light detector and the computer may either be wired (figure 12A) or wireless (figure 12B), wherein the wired system comprises a cable connected between the two devices.

Use of the system for the purpose of detecting cancer and precancerous conditions is merely a statement of intended use and the system disclosed is inherently capable of performing this function.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Perkins, et al (US 6206457). Cook, as discussed above, substantially discloses the invention as claimed, however fails to disclose the use of an LCD display. Cook, for

those limitations not previously discussed discloses a housing that contains the illuminating means and optics as discussed above. Perkins discloses a compact imaging system that includes an integral display (abstract) that may be an LCD screen (claim 61). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Cook in light of the teachings in the reference by Perkins, as inclusion of an LCD screen on the instrument itself advantageously provides a more compact system.

11. Claim 5-9, 30-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Farkas, et al (US 2004/0097790). Cook, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose the use of confocal optics and moving said optics to permit a variable lens distance. Farkas also discloses an endoscope for examining tissue and further teaches a movable lens system (paragraph 15) that provides the ability to image the surface or subsurface (paragraph 13). The lens tube is axially movable relative to the stage from a retracted position to an extended position (figures 5a and 5b). A confocal lens assembly is used in the housing to provide high resolution imaging of both the surface layer and the layers beneath the surface (paragraph 13). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the claims of the prior patent in light of the teachings in the reference by Farkas to include a moving lens system, as Farkas states it is desirable variable magnification of tissue within a body cavity (paragraph 8).

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12. Claims 19, 20, 22, 23, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook, et al. Cook, as discussed above, discloses both the use of LEDs, such as red, green, and blue, and of a monochromatic white light with selectable filters, such as red and green. Cook, however, does not disclose the use of white LEDs or the use of blue filters. It would be an obvious modification, based on the disclosure of Cook to use a white LED and a blue filter, as Cook discloses the use of a variety of light sources including white, red, green, and blue lights. Additionally, Cook discloses the use of both LEDs and filters to provide desired wavelengths. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a white LED and the use of a blue filter to provide the full functionality disclosed by Cook with each type of light source.

13. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Gorti (US 5954658). Cook, as discussed above, substantially discloses the invention as claimed including the use of polarized light. However, Cook fails to disclose the use of depolarized light. Gorti also discloses a system for imaging at precise depths within a tissue. Gorti further teaches that it is known in the imaging art to pass light through a polarizer whose orientation may be adjusted to allow for polarized or depolarized light (col 5, lines 51-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Cook in light of the teachings in the reference by Gorti to include polarized and depolarized scattered light sampling to provide improved images of the target tissue.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jah
4/27/06

Jennifer Horwat
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PRIMARY EXAMINER